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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,844	01/09/2006	Ashwini Kumar Gupta	V0005.70100US00	1829
23628 7590 01/29/2009 WOLF GREENFIELD & SACKS, P.C. 600 ATLANTIC AVENUE BOSTON, MA 02210-2206				
EXAMINER				
MABRY, JOHN				
ART UNIT		PAPER NUMBER		
1625				
MAIL DATE		DELIVERY MODE		
01/29/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/527,844

Applicant(s)

GUPTA ET AL.

Examiner

JOHN MABRY

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 7-9, 26-30 and 33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7-9, 26-30 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 15, 2008 has been entered.

Examiner's Response

Applicant's response on December 15, 2008 filed in response to the Final Office Action dated June 17, 2008 has been received and duly noted.

In view of this response, the status of the rejections/objections of record is as follows:

Status of the Claims

Claims 1-3, 7-9, 26-30 and 33 are pending and rejected.

Claims 4-6, 10-25, 31 and 32 have been cancelled.

Claims 33 is new and rejected.

35 USC § 112 Rejection(s)

The 112-1st rejection of claims 1-3, 7-9, 26-30 and 33 regarding the scope of enablement for R1, R2, R3, R4 and R6, the terms alkenyl, alkynyl, aryl, arylalkyl, arylalkenyl, arylalkynyl, alkylaryl, alkenylaryl, and alkynylaryl which

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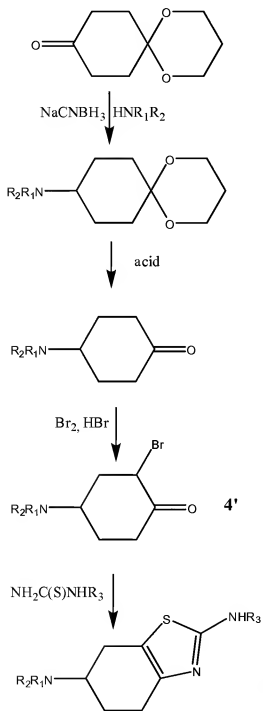
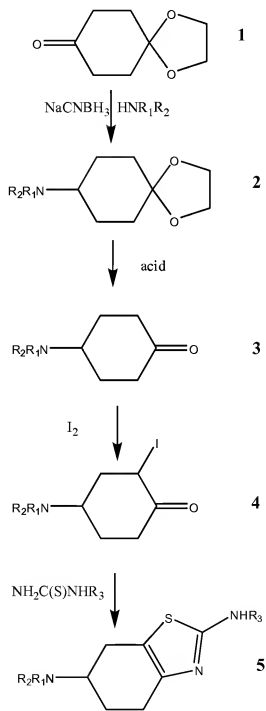
includes heteroatoms in its carbon skeleton have been overcome in view of

Applicants amending the claims.

35 USC § 103(a) Rejection(s)

Applicant's arguments with respect to 103(a) rejections have been fully considered and are not persuasive. The 103(a) rejection of claims 1-3, 7-9, 26-30 and 33 regarding obviousness over Leguzza et al (EP 0207696 A1) in view of Solomons et al (Organic Chemistry, 9th Edition, 2008) remains rejected.

Below is a comparison of the process as described by Leguzza (see pages 7-10) versus the Applicant's claimed process:

Leguzzza**Applicant**

These two processes correlate in every aspect with the exception of the step of converting 3 → 4. Leguzza's disclosure converts aminoketone (3) to the alpha-bromoketone (4') then concentrates the crude reaction mixture of (4'). The crude reaction mixture of (4') is then converted to the final product (5).

The instant application claims a process which converts the aminoketone (3) to the alpha-iodoketone (4) *in situ* then converts (4) to the final product (5).

As clearly describes in previous Non-Final Office Action, the instant application is obvious over the process of Leguzza. An artisan of ordinary skill would be motivated to make the alpha-iodoketone (4) in place of the alpha-bromoketone (4') because I⁻ (iodide) is a better leaving group compared to Br⁻ (bromide) as described by Solomons. One of ordinary skill in the art would be further motivated to convert the alpha-haloketone to the desired product (5) to (a) increase the yield and (b) more facile way of achieving the desired product (one less step). Thus, the instant application is rendered obvious over Leguzza in view of Solomons.

Additionally, claims 1-3, 7-9, 26-30 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leguzza in view of Solomons in references mentioned above. The adjustment of particular conventional working conditions (e.g. determining result effective amounts of the ingredients beneficially taught by the cited references), as well as adjustment of reaction temperature, reaction time and use of solvents, is deemed merely a matter of judicious selection and

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routine optimization which is well within the purview of the skilled artisan (*In re* Mostovych, Weber, Mitchell and Aulbach, 144 USPQ 38). Accordingly, these types of modifications would have been well within the purview of the skilled artisan and no more than an effort to optimize results.

Applicant argues the one of ordinary skill in the art would expect for use of the iodine in Leguzza process would produce an alpha-iodoketone that is highly unstable, relative to the corresponding alpha-bromoketone. Examiner respectfully disagrees. One of ordinary skill in the art would expect for the alpha-iodoketone to react more facile thus potentially producing a higher yield, since iodide is a better leaving than bromide.

In view of that fact, one of ordinary skill in the art would expect for the alpha-iodoketone to produce a higher yield, there really is not much a yield different between the process of Leguzza's and Applicant's claimed invention. For example, Leguzza produces the compound, N⁶,N⁶-dipropyl-4,5,6,7-tetrahydrobenzo[d]thiazole-2,6-diamine•2HBr, which falls within the claimed scope (see page 13, lines 15-30, page 14, lines 1-8 and page 15, lines 20-29). The process of Leguzza's produces a 50% yield. In the experimental section of Specification, Applicant produces 2-Amino-6-n-propylamino-5,6,7,8-tetrahydrobenzthiazole•2HI in a 56% yield. Applicant has also failed to make a significant contribution of the prior art.

The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in KSR noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that “[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” KSR, 550 U.S. at ___, 82 USPQ2d at 1396. Exemplary rationales that may support a conclusion of obviousness include:

- (A) Combining prior art elements according to known methods to yield predictable results;
- (B) Simple substitution of one known element for another to obtain predictable results;
- (C) Use of known technique to improve similar devices (methods, or products) in the same way;
- (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (E) “Obvious to try” – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- (F) Known work in one field of endeavor may prompt variations of it for use in

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either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;

- (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention. See MPEP § 214.3 for a discussion of the rationales listed above along with examples illustrating how the cited rationales may be used to support a finding of obviousness. See also MPEP § 2144- §2144.09 for additional guidance regarding support for obviousness determinations.

The aforementioned reasons above describe rationales that support a conclusion of obviousness based upon the KSR International Co. v. Teleflex Inc. decision. At least letters (A) - (G) rationale is supported above.

Claim Rejections - 35 USC § 102

Claim 31 is rejected under 35 U.S.C. 102(b) as being anticipated by Yokum et al (Tet. Lett. 1997, 38, 4013-4016) has been overcome in view of Applicant cancelling the claim.

Claim Rejections - 35 USC § 103

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yokum et al (Tet. Lett. 1997, 38, 4013-4016) has been overcome in view of Applicant cancelling the claim.

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Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Mabry, PhD whose telephone number is (571) 270-1967. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, PhD, can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/John Mabry/
Examiner
Art Unit 1625

/Rita J. Desai/
Primary Examiner, Art Unit 1625